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APPLICATION NUMBER: ***60/556,152***
FILING DATE: ***March 25, 2004***
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

Case No. **HAUS.002PR**
Date: March 25, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTENTION: PROVISIONAL PATENT APPLICATION

Sir:

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR § 1.53(c).

For: **VASCULAR FILTER DEVICE**

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Residence Address:	Newport Beach, California
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Residence Address:	Los Angeles, California .

Enclosed are:

(X) Specification in 12 pages.

(X) 17 sheet(s) of drawings.

(X) A check in the amount of $80 to cover the filing fee is enclosed.

(X) A return prepaid postcard.

(X) The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment to Account No. 11-1410.

Was this invention made by an agency of the United States Government or under a contract with an agency of the United States Government?

(X) No.

( ) Yes. The name of the U.S. Government agency and the Government contract number are:

(X) Please send correspondence to:

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Attorney Docket No.	:	HAUS.002PR
Applicant(s)	:	Hauser, et al.
For	:	VASCULAR FILTER DEVICE
ATtorney	:	David L. Hauser
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Date of Deposit	:	March 25, 2004

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Transmittal letter; specification in 12 pages; 17 sheets of drawings; Check for Filing Fee; Return Prepaid Postcard

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Nelson Merida

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VASCULAR FILTER DEVICE

Background of the Invention

Field of the Invention

[0001] The present invention relates generally to vascular filters and, more particularly, the invention relates to a filter device for placement within a blood vessel that is adapted to capture and remove embolic material from the blood.

Description of the Related Art

[0002] Vascular filters are used in a wide variety of purposes wherein it is desirable to capture particles from the blood. One primary use of vascular filters is to reduce the likelihood of a pulmonary embolism. For this purpose, a vascular filter is implanted within a vein, typically the inferior vena cava, for capturing large blood clots before they can reach the pulmonary vasculature.

[0003] Most often, a vascular filter is implanted within the inferior vena cava from a variety of peripheral vein access sites, for example, the jugular or femoral veins. An early example of such a filter is the Mobin-Uddin ("MU") umbrella filter, which was developed and made available by American Edwards Laboratories in Santa Monica, Calif. in the 1970s. The Mobin-Uddin umbrella was composed of six flat ELGILOY spokes radiating from a hub and partially covered by a web designed to capture blood clots. MU filters were introduced into the body via a cutdown of the jugular or femoral vein and subsequent passing of a catheter through the access site to the filter implant site in the infrarenal inferior vena cava. While this method was an improvement over previous methods, the MU filter was associated with a high incidence of occlusion of the inferior vena cava, in which blood flow through the vena cava was completely obstructed.

[0004] In the mid-1970's, the Kimray-Greenfield ("KG") vena cava filter was introduced. The original KG filter is conical in shape and is composed of six stainless steel wires equally spaced with its apex cephalad. Although the filter was originally placed using a local cutdown of the jugular or femoral vein, it was later adapted to be inserted percutaneously. A variety of KG filters were produced; however, the KG filter is typically designed to capture clots 7 mm or greater in diameter, holding the clots in the infrarenal vena

cava until the body's own lytic system dissolves the clot. The principal drawbacks of the KG filter are the possibility of tilting, clogging and filter migration, often related to a failure to open, or untimely ejection of the filter from the introducer.

[0005] Subsequent versions of the so-called Greenfield filter were developed to reduce the size of the introducer catheter to facilitate percutaneous introduction. Other vena cava filters were introduced in the United States in the late 1980s, including the Vena Tech--LGM vena cava filter, the Bird's Nest vena cava filter, and the Simon-Nitinol vena cava filter. The Vena Tech--LGM filter is a conical filter made from the PHYNOX alloy, with longitudinal stabilizing legs in addition to the intraluminal cone. The Bird's Nest filter is a "nest" of stainless steel wire which is wound into the vena cava, while the Simon Nitinol filter is a two-stage filter made from nickel-titanium alloy with a conical lower section and a petal-shaped upper section. Each of these devices is adapted for permanent implantation and cannot be removed from the body without a major surgical intervention.

[0006] Among numerous vena cava filters introduced in Europe but never brought to the United States was the optimal central trapping (OPCETRA) filter. The OPCETRA filter has two main parts: a main basket with ten, long stainless steel wire arms and a distal basket with five, short stainless steel wire arms. This design gives the filter an hourglass shape that provides a self-orienting structure for the filter within the lumen of a blood vessel. The OPCETRA filter was also a permanently implanted vena cava filter.

[0007] The above-identified vena cava filters are inserted into the body by passing the filter through a catheter to the site of deployment in the infrarenal inferior vena cava. After ejection from the catheter, these filters open or are manually deployed until the filter anchoring elements engage the vessel wall. These filters often have hooks or some other means by which the filter becomes fixed permanently to the vessel wall.

[0008] For an important subset of patients, in particular young trauma patients and patients undergoing total hip or knee replacement surgery, the risk of embolism is short-term and limited to a definable period of time. Because of the long-term risks associated with implantation of a permanent blood filter, including venous stasis due to caval occlusion and its related complications, patients whose risk period is limited are not considered good

candidates for permanent blood filters. The search for an appropriate temporary therapy for such patients lead to the development of temporary, tethered removable filters.

[0009] Tethered temporary filters are attached to a catheter and are implanted in the infrarenal vena cava with the tethering catheter extending out of the puncture site in the neck or groin, or buried subcutaneously within the soft tissues in the patient's neck. The tether remains coupled to the filter after deployment. The tether is then used to retrieve the filter. The potential for septic complications associated with the tethering catheter exiting the neck or groin require removal of such devices within fourteen days of placement. Risk periods for embolism in such patients, however, can extend up to twenty-one weeks.

[0010] Temporary retrievable filters which are not attached to a tethering catheter have a construction similar to some versions of permanent filters. A hook or similar grasping structure is provided to allow a snare to engage the filter during the retrieval procedure. The filter in its entirety is then retrieved using a snare by drawing it into a catheter. However, to ensure the filter does not migrate within the vessel, barbs, anchors or similar structures must be used to engage the filter with the interior wall of the vessel for retaining it in place. These anchors make removal without injuring the vessel difficult. Moreover, after a relatively short period of time the portion of the filter legs in contact with the vessel wall are incorporated by endothelial tissue making retrieval difficult or impossible.

[0011] More recently, it has been proposed to provide a removable filter in two parts. An anchoring part of the filter engages the vessel walls, and become incorporated by endothelial tissue. A filter part is releasably coupled to the anchoring part. After the risk of embolism has passed, the filter part may be retrieved using a snare and catheter.

[0012] Although filters, such as those described above, have met with considerable success, existing filter configurations suffer from a variety of shortcomings that limit their effectiveness. In one primary shortcoming, blood filters are susceptible to clogging with embolic material. When a filter becomes partially or totally occluded, the blood flow through the filter is substantially reduced or stopped completely. Serious complications can arise when this occurs. When clogging occurs, the patient must be treated immediately to restrore blood flow. To reduce the likelihood of clogging, filters are typically manufactured with relatively large pores such that only large emboli are captured.

Accordingly, in another shortcoming, filters of this type fail to prevent the passage of smaller emboli, which are still capable of causing serious damage.

[0013] Thus, there is a need for an improved blood filter that is configured to reduce the likelihood of clogging. The present invention addresses this need.

Summary of the Invention

[0014] The present invention provides a vascular filter device adapted for capturing, retaining and breaking down embolic material from the blood.

[0015] Preferred embodiments of the present invention generally comprise an expandable filter device shaped for capturing embolic material. The filter device preferably includes a filter body and a rotating element. Anchoring may be included for providing a means for anchoring the filter body in a blood vessel. The rotating element preferably includes a cutting element. The cutting element and the filter body cooperate to act on and break apart emboli captured within the interior volume of the filter. The filter device is preferably configured such that the flow of blood through the filter device causes the rotating element to move relative to the body.

[0016] In one embodiment, the rotating element is a helical body. The helical body is acted upon by the blood flow through the blood vessel for causing the helical body to rotate. The helical body may be located downstream of the filter body, upstream of the filter body, or may be located within the interior volume of the filter device. The helical body is coupled to a cutting element that is located within the interior volume of the filter device. The cutting element is configured to act on embolic material contained within the filter device. The cutting element in the interior volume may take a wide variety of shapes adapted for acting on the clot, such as by catching, hooking, snagging or grinding. Alternatively, the helical body itself may act as the cutting element.

Brief Description of the Drawings

[0017] Figure 1 illustrates one method of deploying a filter device in a blood vessel for capturing emboli.

[0018] Figure 2 is a side view illustrating a self-cleaning vascular filter according to one preferred embodiment of the present invention.

[0019] Figure 3 is a side view illustrating the self-cleaning vascular filter of FIG.2 and further comprising barbs along the inner body for helping to break apart emboli.

[0020] Figures 4-6 illustrate the vascular filter of FIG. 3 during use.

[0021] Figures 7 and 8 illustrates alternative embodiments of a force receiving mechanism for causing the movable element to rotate.

[0022] Figure 9 illustrates the vane of FIG. 7 used with a vascular filter.

[0023] Figure 10 illustrates the vascular filter of FIG. 9 and further comprising anchoring elements.

[0024] Figure 11 illustrates a vascular filter including a support wire which also may be used to help cut through embolic material.

[0025] Figure 12 illustrates an alternative embodiment wherein a rotating element is provided within the filter body, the rotating element including cutting means.

[0026] Figure 13 illustrates another alternative embodiment wherein a spring couples the rotating element to the filter body to allow limited longitudinal movement between the two.

[0027] Figure 14 illustrates another alternative embodiment wherein a rotating element comprises vanes.

[0028] Figure 15 illustrates another alternative embodiment wherein the vascular filter is provided with a rotating element that is capable of reversing direction.

[0029] Figure 16 illustrates another alternative embodiment wherein the rotating element comprises a tapered helical body.

[0030] Figure 17 illustrates another alternative embodiment wherein the rotating element comprises a tapered helical body that is truncated and further includes a cutting means.

[0031] Figure 18 illustrates the vascular filter of FIG. 17 in an assembled condition.

Detailed Description of the Preferred Embodiments

[0032] Preferred embodiments of the present invention provide an apparatus and method for capturing and breaking apart blood clots (or other particles) within a patient's vasculature.

[0033] Referring to FIG. 1, for background purposes, one method of using a filter device 10 to filter particles from the inferior vena cava is illustrated. The filter may be temporarily deployed or permanently deployed in the vessel. The filter device is shown is a deployed condition wherein emboli and/or thrombi are filtered from the inferior venal caval 12 using a filter body 13. When expanded, the filter body defines an interior volume shaped for capturing and containing particles. In the illustrated embodiment, the filter body 13 comprises a mesh-like, collapsible basket connected to the distal end 20 of the inner catheter 17 in such a way that when it is deployed (opened), the patient's blood can flow through the filter body to the patient's heart.

[0034] Referring now to Figure 2, one preferred embodiment of an improved system for capturing and breaking apart emboli generally comprises a filter device 100 adapted for placement in a blood vessel 102 comprising a filter body 104 and a movable element 106. In the illustrated embodiment, the movable element 106 includes a corkscrew shaped member 108 and a flow receiving member 110. The corkscrew shaped member 108 is located within an interior volume of the filter body 104 and includes a first end 112 and a second end 114. The first end preferably includes a pointed tip for penetrating embolic material. The second end 114 is fixed to the flow receiving member 110. As the flow of blood through the vessel passes the flow receiving member 114 (shown by arrow), the hydrodynamic forces acting on the flow receiving member cause the entire movable element 110 to rotate. However, the filter body 104 remains substantially fixed with respect to the blood vessel 102.

[0035] With reference to FIG. 3, another embodiment of a self-cleaning filter device is illustrated. In this embodiment, one or more inner barbs are provided along the inner wall of the filter body for digging into and tearing the embolus as it is forced deeper into the filter by the rotating member.

[0036] Referring now to FIGS. 4-6, the filter device illustrated above in FIG. 3 is shown during use. When an embolus (or thrombus or other particle in the blood) 200 reaches the filter device 100, the embolus 200 is funneled toward the center of the filter body 104. The flow of blood moves the embolus 200 into contact with the first end 112 of the corkscrew shaped member 108. The tip of the corkscrew shaped member 108 penetrates the

embolus and begins to draw the embolus downward, as shown in FIG. 4. FIG. 5 illustrates the embolus as it is drawn further into the filter body wherein it is acted on by barbs 120 that penetrate and thereby help break apart the embolus. As the embolus is drawn further into the filter, pieces 202 of the embolus break away. The barbs also prevent the embolus from rotating with the corkscrew shaped member, thereby ensuring that the embolus is drawn further into the filter body. When the embolus 200 reaches the wall of the filter body, as shown in FIG. 6, the continued motion of the corkscrew shaped member continues to impart mechanical forces on the embolus, thereby causing it to compress and eventually break apart into harmless smaller particles. As the embolus is broken into smaller pieces, the body's own thrombolytic capabilities are able to safely and effectively dissolve the remaining pieces. The remaining particles may be held within the filter body or the filter body may be configured with a pore size sufficient to allow the harmless smaller particles to pass through the filter wherein they may be dissolved downstream.

[0037] It is recognized that the corkscrew shaped member may not penetrate all emboli that enter the filter body. However, even if a particle enters the region between the corkscrew shaped member and the filter body, the corkscrew shaped member will still act on the particle and cause it to break apart over time.

[0038] Although the movable element is illustrated as comprising a rotatable corkscrew shaped member and a flow receiving member, any configuration of a movable element may be used that is configured for breaking down a particle within the filter body. FIGS. 7 and 8 illustrate additional types of flow receiving members that may be used to transfer energy from the blood to cause the movable element to move. It is desirable that the flow receiving member be configured to disrupt the flow of blood as little as possible and damage to the fragile blood cells is kept to a minimum. Preferably, the flow of blood should remain laminar as it passes through the filter. The flow receiving member may be located upstream or downstream of the filter body. Alternatively, the flow receiving member may be located within the filter body. Still further, the corkscrew or other means for acting on the embolus may be configured for receiving force itself. For example, a threaded structure similar to an "Archimedes screw" may be employed.

[0039] FIG. 9 illustrates another embodiment of a self-cleaning vascular filter. In this embodiment, a shaft extends through the central region of the corkscrew shaped member. The shaft is fixed (non-rotating) with respect to the filter body and may include prongs for further breaking apart the embolus.

[0040] FIG. 10 illustrates anchoring elements disposed along the rim of the filter body. In various alternative embodiments, the anchoring elements may take a variety of different forms. Preferably, the anchoring elements comprise hooks configured to engage the inner surface of the vessel.

[0041] FIG. 11 illustrates yet another embodiment of a filter device further comprising a thin wire extending across the filter body. The thin wire provides additional support to the rotating corkscrew member. Furthermore, the thin wire provides a cutting means for facilitating the disintegration of the embolic material.

[0042] FIG. 12 illustrates yet another alternative embodiment of a filter device configured for breaking apart embolic material. In this embodiment, the filter device comprises a filter body and a central rotating member. The rotating member is configured to rotate as blood flows through the filter. In the illustrated embodiment, fins are provided for translating the force of the blood flow into rotational motion. The rotating member is provided with teeth, threads, hooks or other means for mechanically acting on embolic material as it enters the filter body.

[0043] FIG. 13 illustrates another alternative embodiment that is further provided with at least one resilient member for allowing the rotating member to move or "pulse" axially. The axial movement may be caused by fluctuation in the flood of blood and further assists the rotating member to grind up the embolic material.

[0044] FIG. 14 illustrates another alternative embodiment comprising a rotating element including a plurality of vanes that are substantially parallel with the wall of the filter body. The vanes are configured to impart a force on the rotating element.

[0045] FIG. 15 illustrates another alternative embodiment wherein the rotating element is capable of reversing direction. First and second vanes extend laterally across the opening to the filter. Projections are provided at the ends of the vanes, which are received by openings along the rim of the filter body. The openings are configured such that the

projections may rotate (i.e., readjust) within the openings. When the projections settle in a first position, the vanes are positioned to cause the rotating element to rotate in a first direction. When the projections are turned 90 degrees and settle again, the vanes are then positioned to cause the rotating element to rotate in a second direction. After being implanted in a vessel, the vane positions may be readjusted by the patient's movements. Alternatively, the fluctuations in the blood flow may cause the vanes to readjust. In any event, the reversibility of the vanes advantageously reduces the possibility of clogging or jamming of the rotating element within the filter body.

[0046] FIG. 16 illustrates yet another embodiment wherein the rotating element takes the form of a tapered helical element. The helical element rotates as blood flows through the filter. The rotation of the helical element continually acts on embolic material trapped within the filter, thereby causing the material to break down into smaller and less harmful particles.

[0047] FIG. 17 illustrates yet another embodiment that is similar to the filter of FIG. 16. However, the helical portion of the rotating element is truncated. A cutting means is provided along the downstream portion of the rotating element, which acts on trapped embolic material. In the illustrated embodiment, the cutting means comprises a plurality of wires configured in a "fishbone arrangement." The wires may be flexible such that the cutting means cannot become jammed against a trapped particle. The cutting means is configured to break apart the trapped particle(s) as the rotating element is caused to turn by the flow of blood. A support structure may be provided along the upstream end of the filter for maintaining the rotating element is the desired alignment with respect to the filter body. FIG. 18 illustrates the vascular filter of FIG. 17 in an assembled condition.

[0048] Preferred embodiments of the filter device are configured to be collapsible for delivery to a treatment site. The filter device is collapsed to fit within a lumen of a delivery catheter. Preferably, the filter device is self-expanding such that it expands to engage the inner surface of the vessel after delivery.

[0049] Preferred embodiments of the filter device are made of a shape-memory and/or super elastic material for enabling self expansion at the treatment site. Nitinol may be used.

[0050] Although the improvements disclosed herein are primarily discussed in the context of use with a vascular filter, the improvements may also be applicable to a wide variety of other applications. For example, a self-cleaning filter may be used in any application wherein it is desirable to capture and break apart particles. The device may be used with any fluid, whether a solid or a gas. Preferably, any fluid will be applicable wherein the fluid is capable of causing the rotating member to rotate or otherwise move relative to another structure.

[0051] In another alternative embodiment, the movable element may be driven by an external source of power, rather than the flow of blood.

[0052] While the foregoing detailed description has described several embodiments of the apparatus of the present invention, it is to be understood that the above description is illustrative only and is not limiting of the disclosed invention. It will be appreciated that the specific features of the invention can differ from those described above while remaining within the scope of the present invention. For example, the present invention is intended to include any filter device having a movable component within the interior volume for breaking apart captured particles and thereby providing a self-cleaning device. The movable component may be powered by the flow of a fluid through the filter or by an internal or external source of power.

WHAT IS CLAIMED IS:

1. A vascular filter, comprising:

a filter body forming an interior volume when deployed, said interior volume configured for capturing particles from a patient's blood; and

a rotating element rotatably coupled to the filter body, the rotating element being caused to rotate by blood flow through the filter body;

wherein said rotating element moves relative to said filter body for breaking down the captured particles.

2. The vascular filter of Claim 1, wherein said filter body is anchored to an inner wall of a blood vessel.

3. The vascular filter of Claim 2, wherein said rotating element includes a cutting apparatus within said interior volume for acting on the particle.

4. The vascular filter of Claim 1, wherein said rotating element is capable of reversing direction.

5. The vascular filter of Claim 1, wherein said rotating element comprises a least one vane and a cutting element, said vane shaped to rotate said cutting element when acted upon by the flow of blood through the blood vessel.

VASCULAR FILTER DEVICE

Abstract of the Disclosure

A vascular filter for capturing emboli from a blood vessel. The filter includes a rotatable element that is driven by the flow of blood through the vessel. The rotatable element acts on emboli trapped in the filter and helps break them apart, thereby preventing the filter from becoming clogged.

PROVISIONAL PATENT

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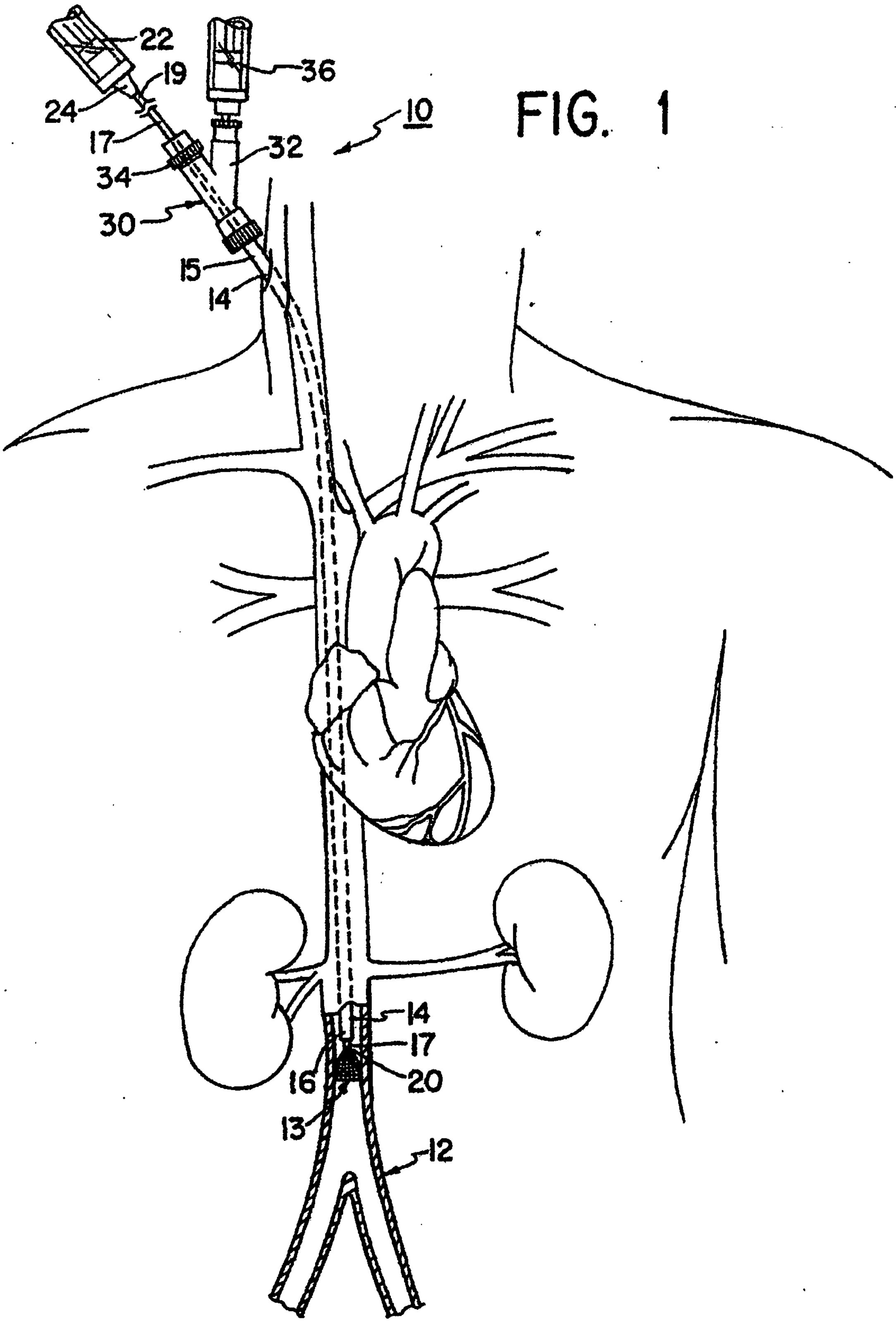
FIG. 1



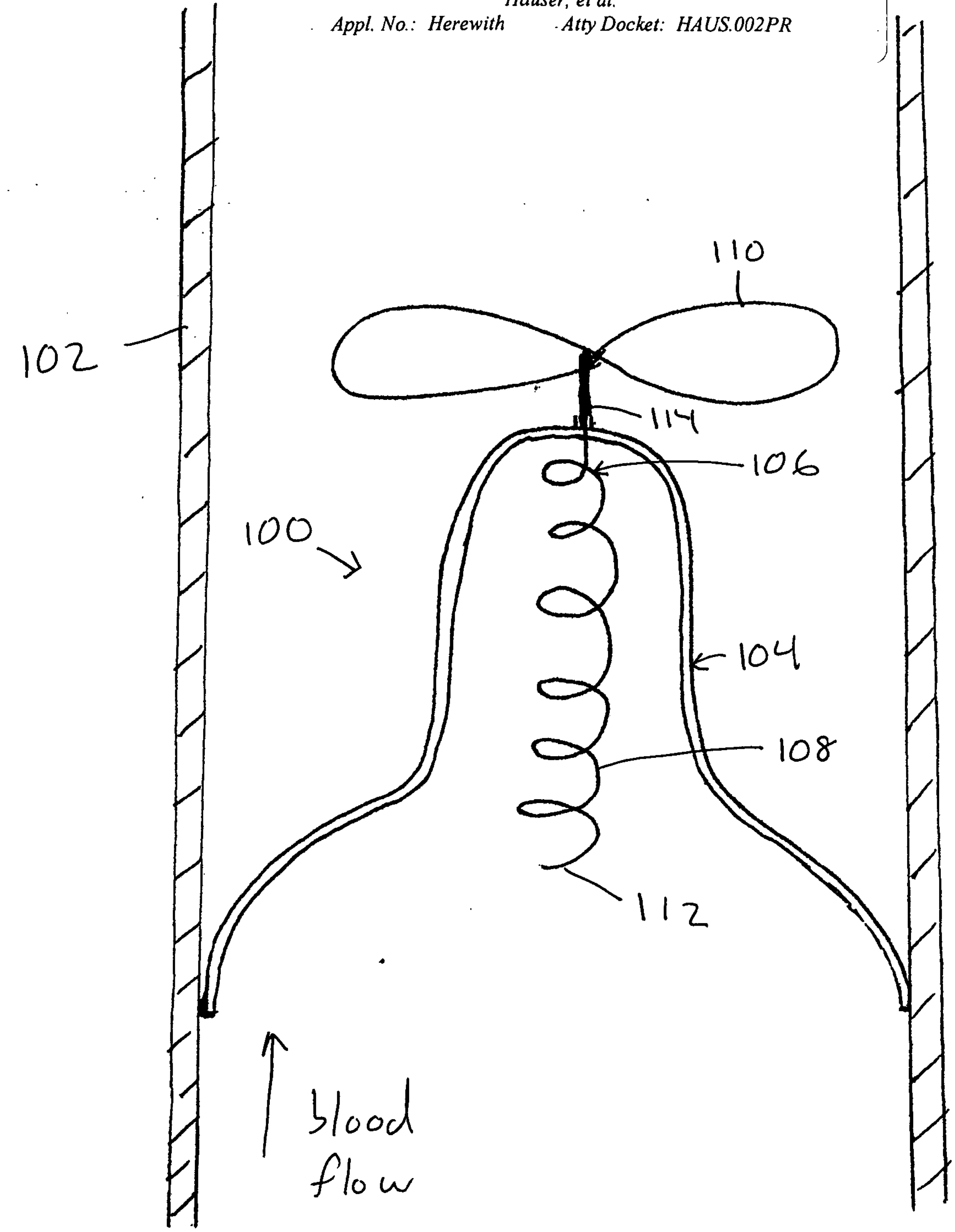


FIGURE 2

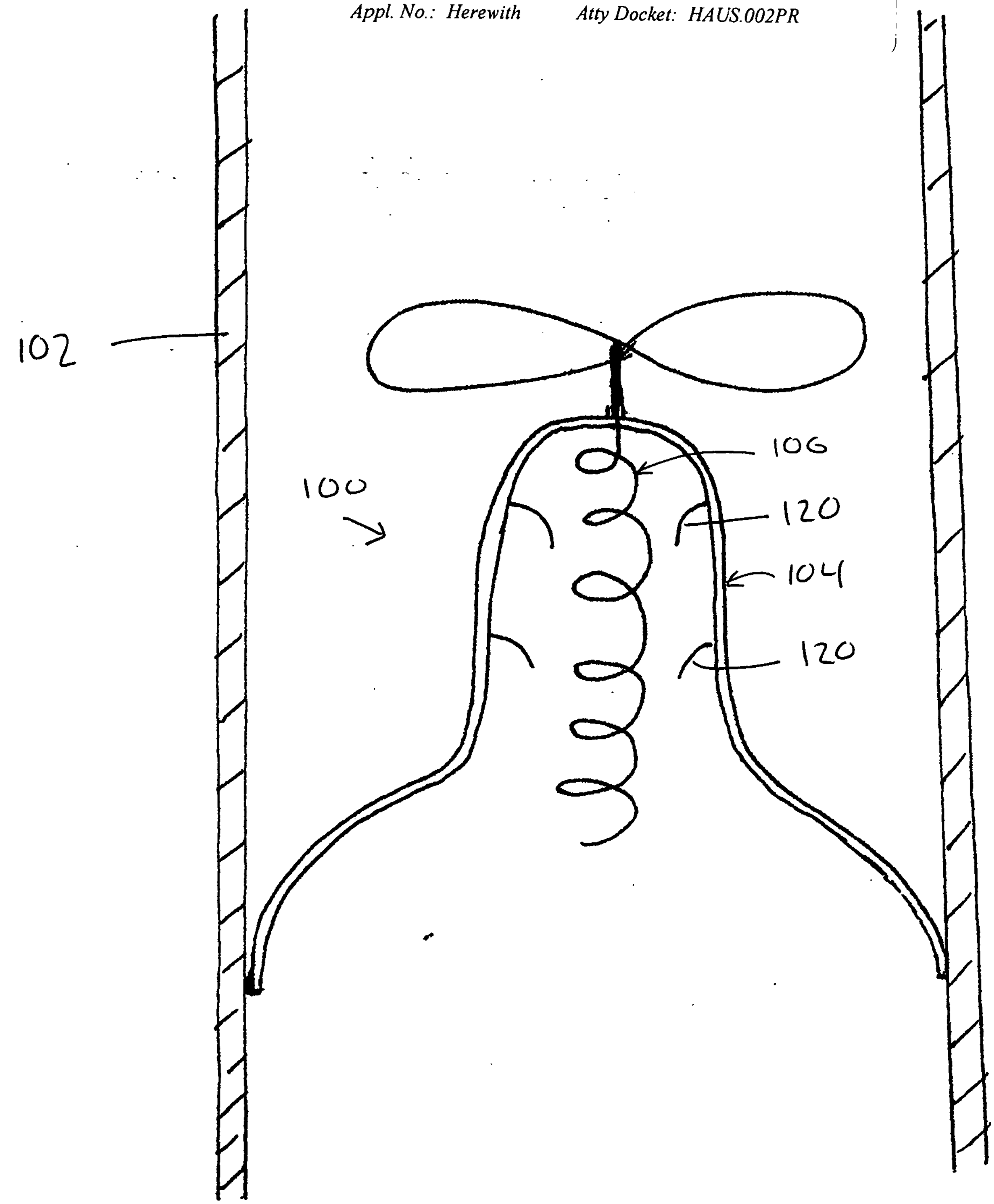


FIGURE 3

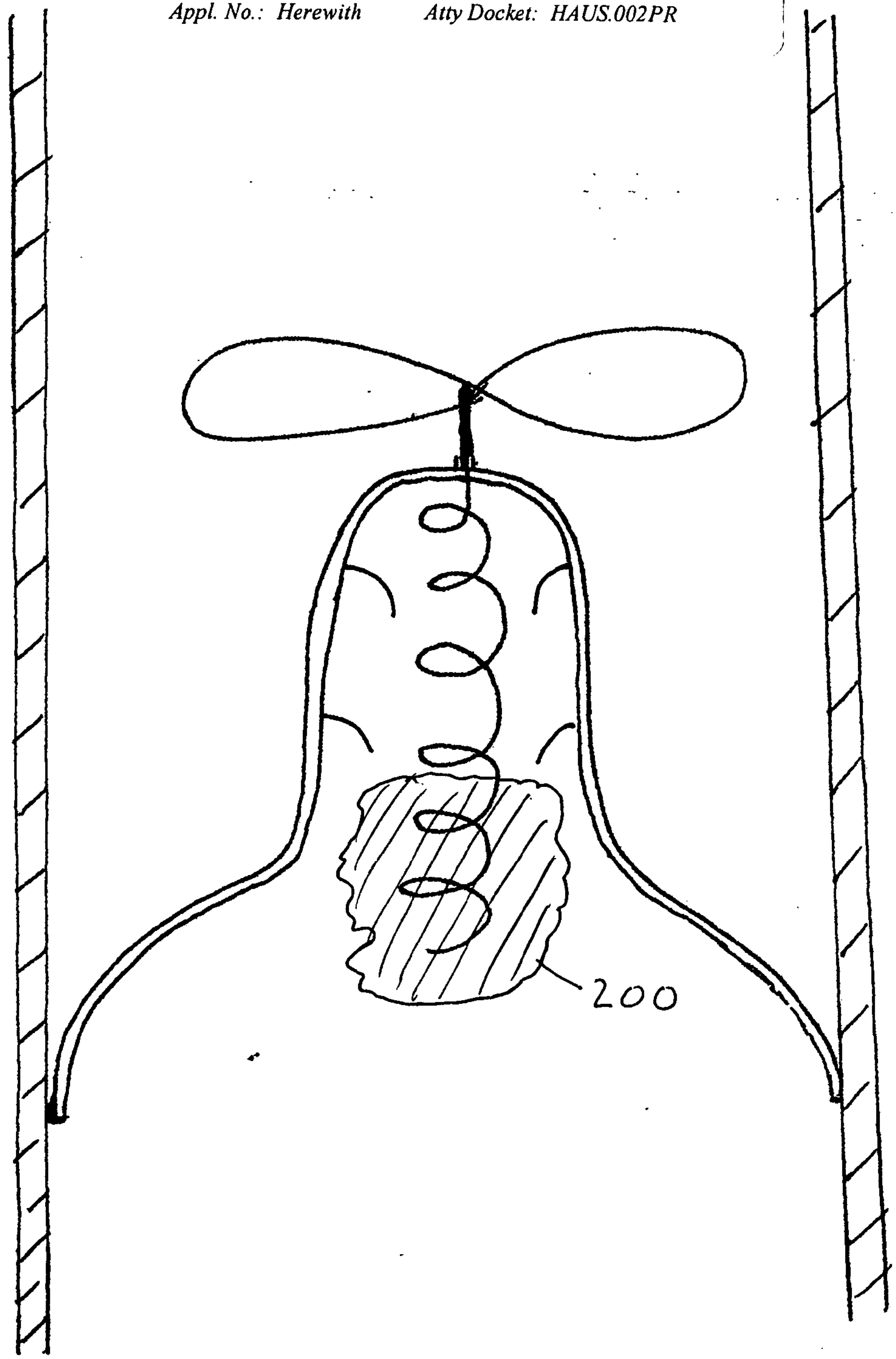


FIGURE 4

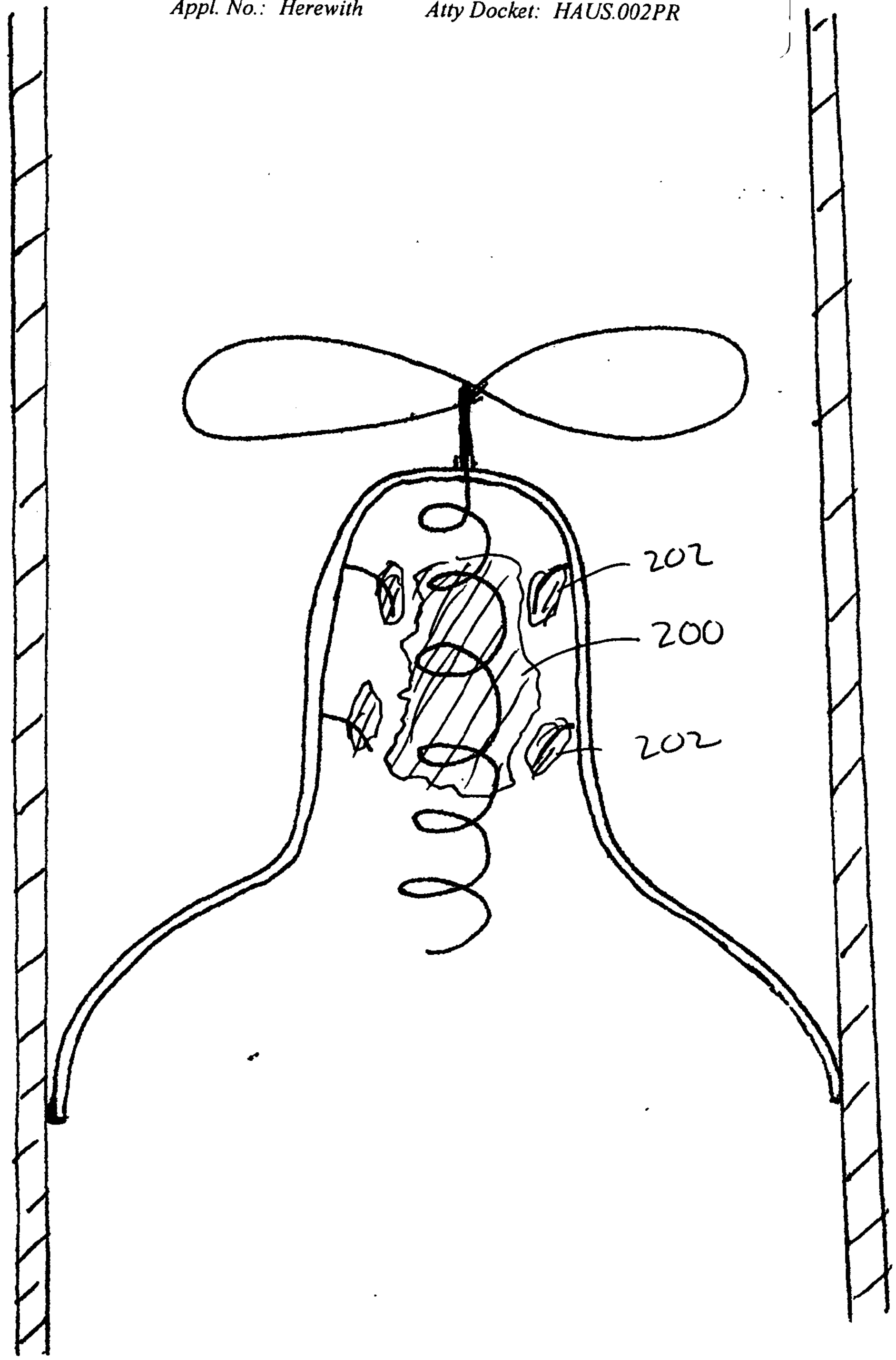


FIGURE 5

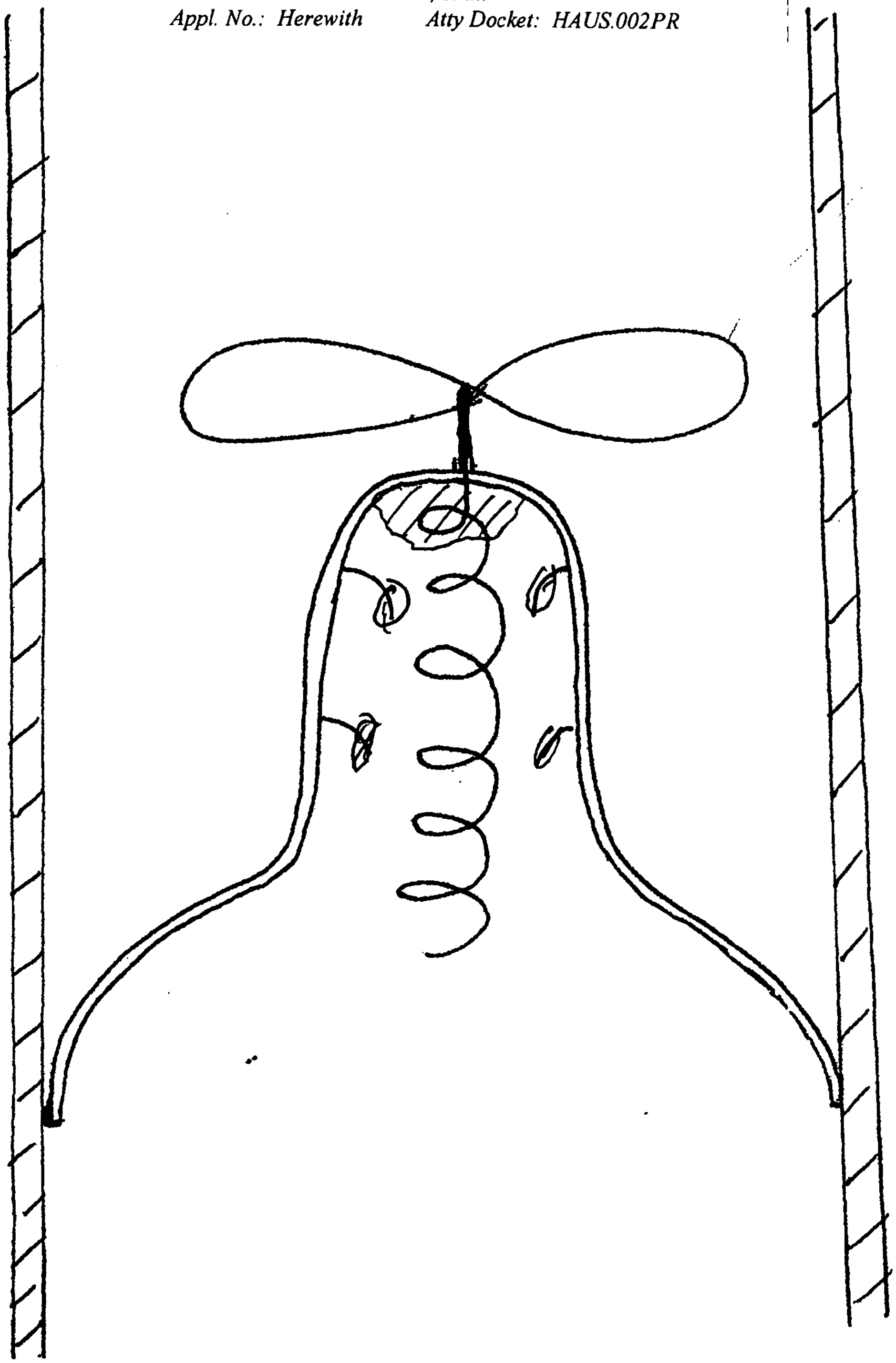


FIGURE 6

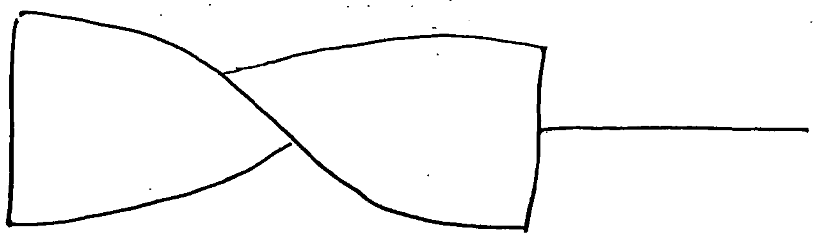


FIGURE 7

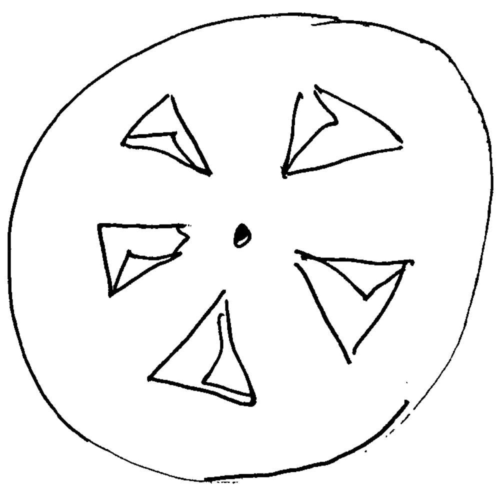


FIGURE 8

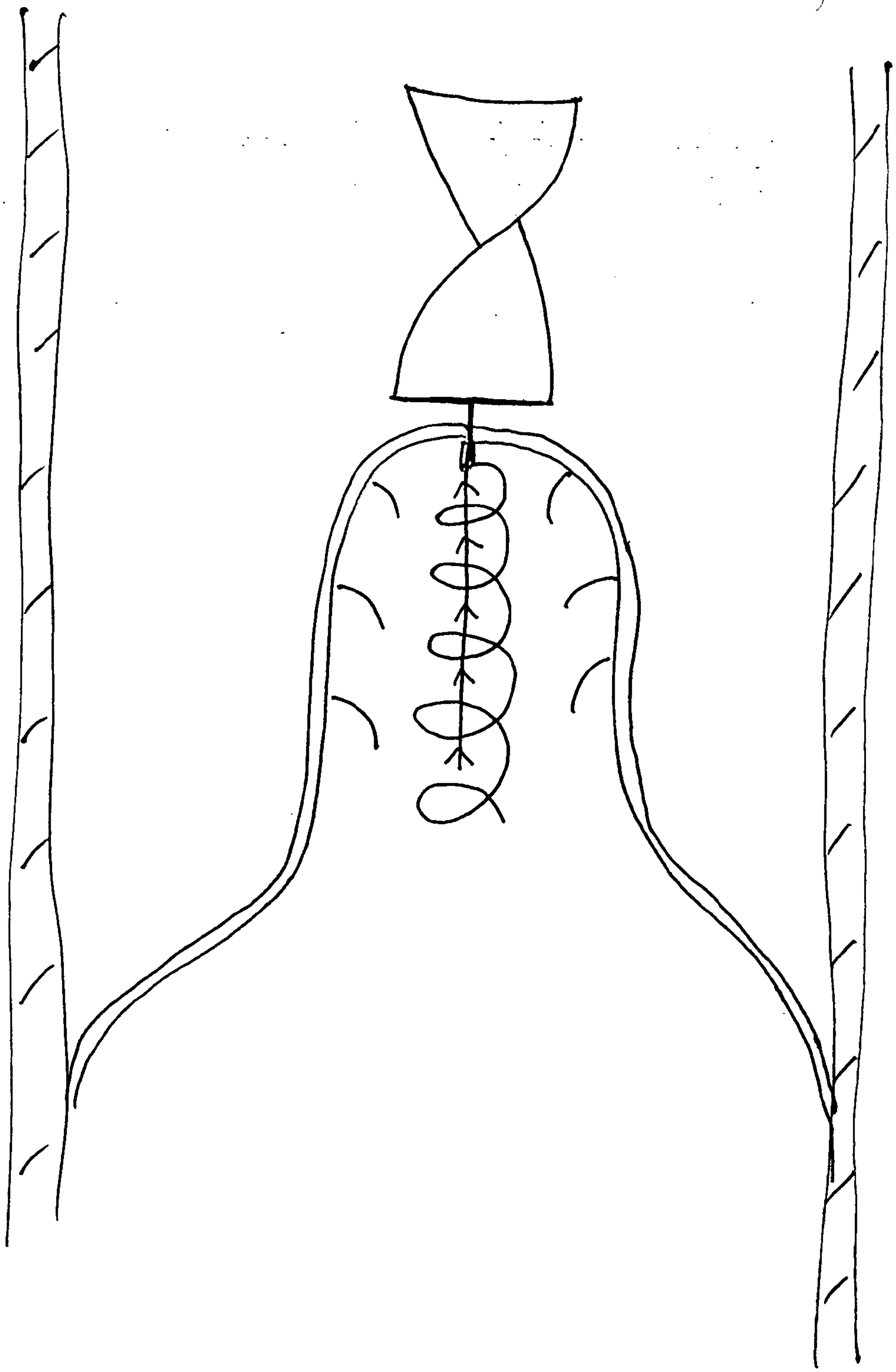


FIGURE 9

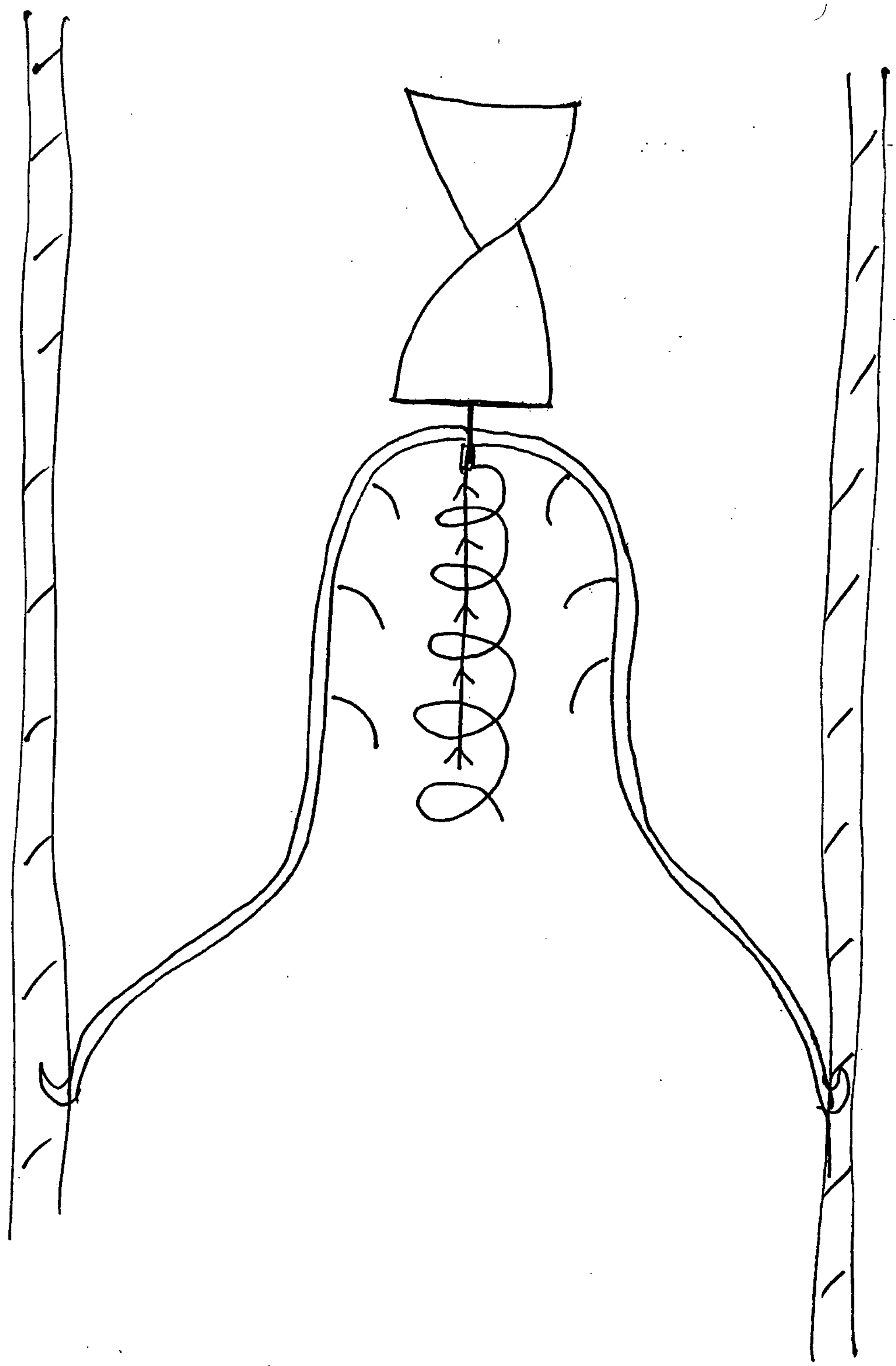


FIGURE 10

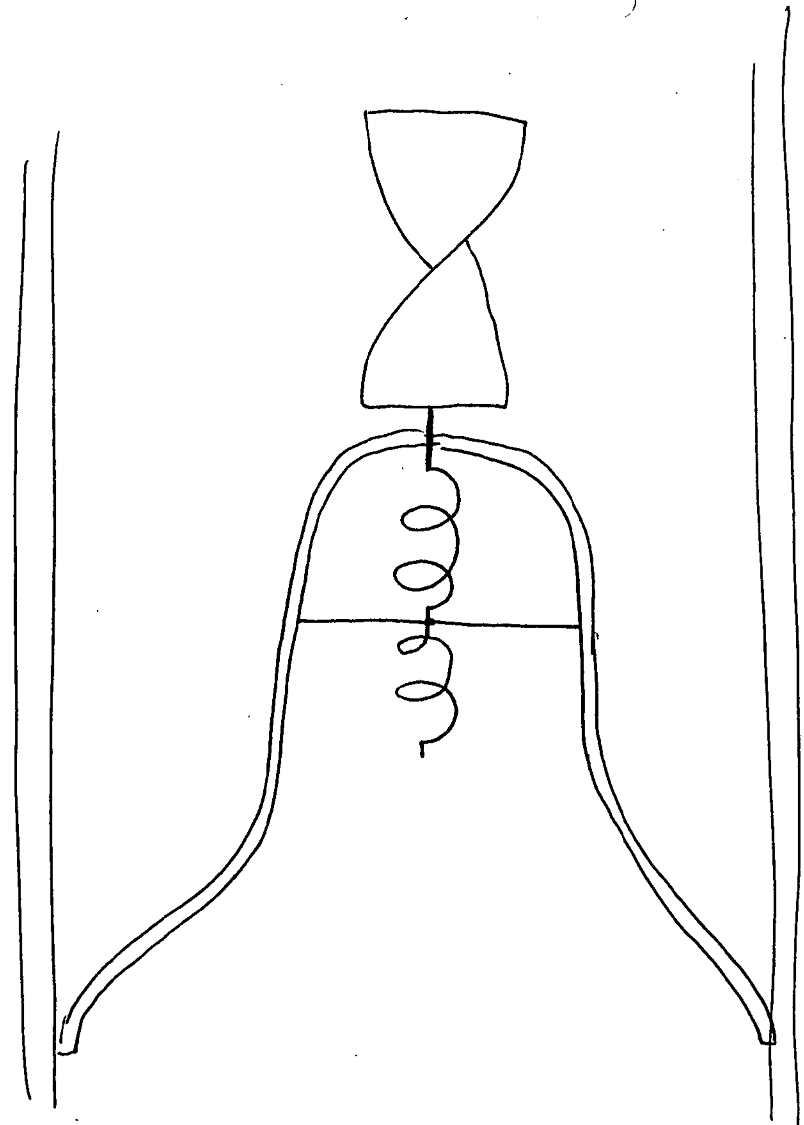


FIGURE 11

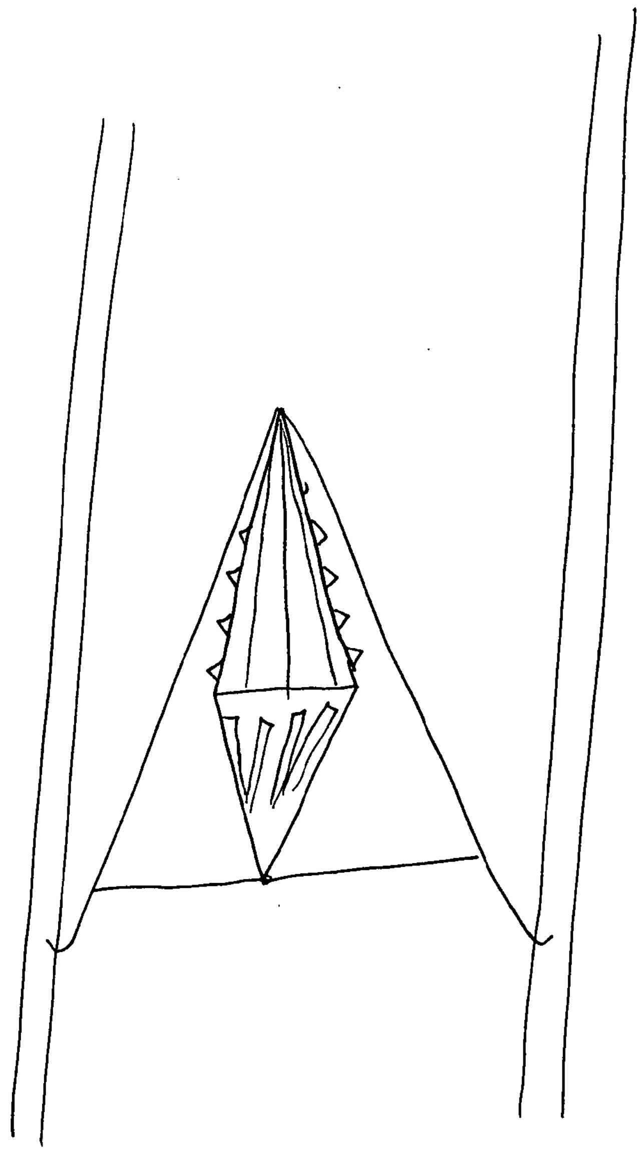


FIGURE 12

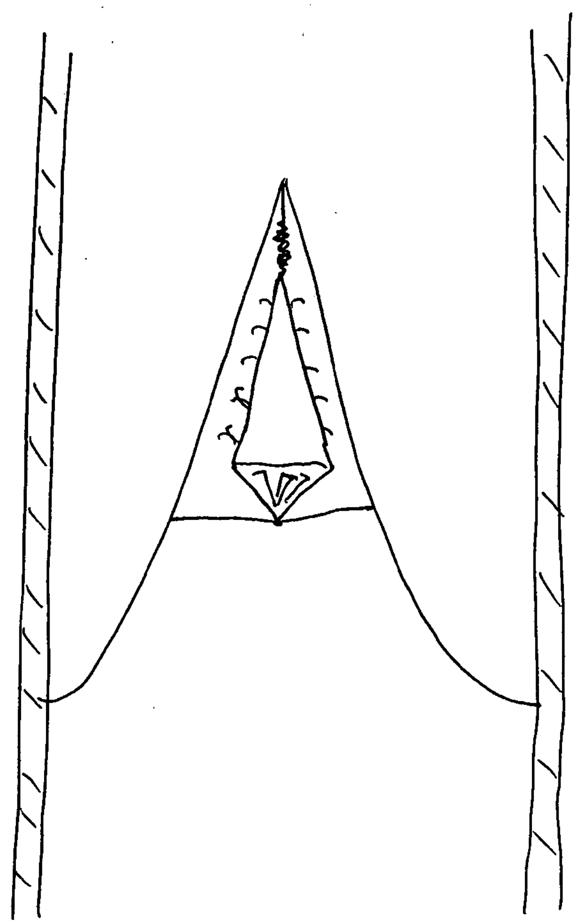


FIGURE 13

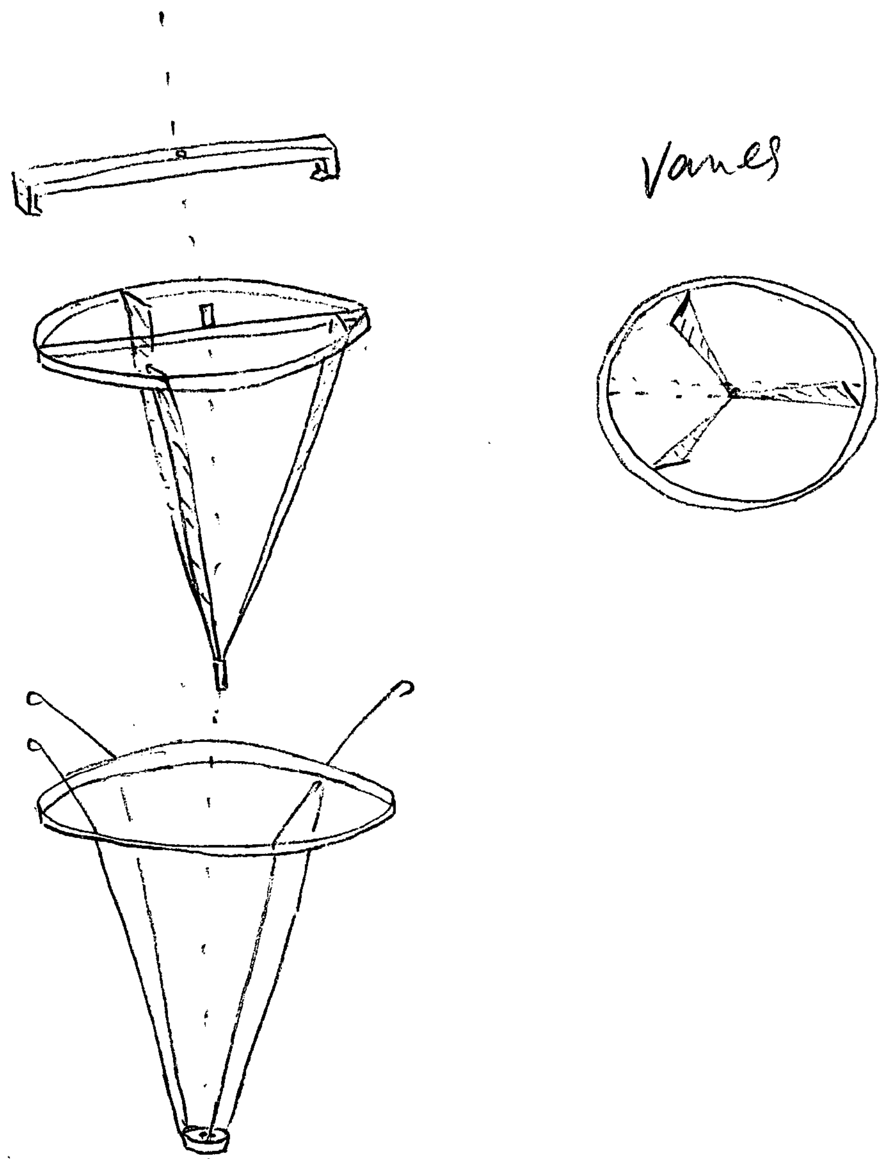


FIGURE 14

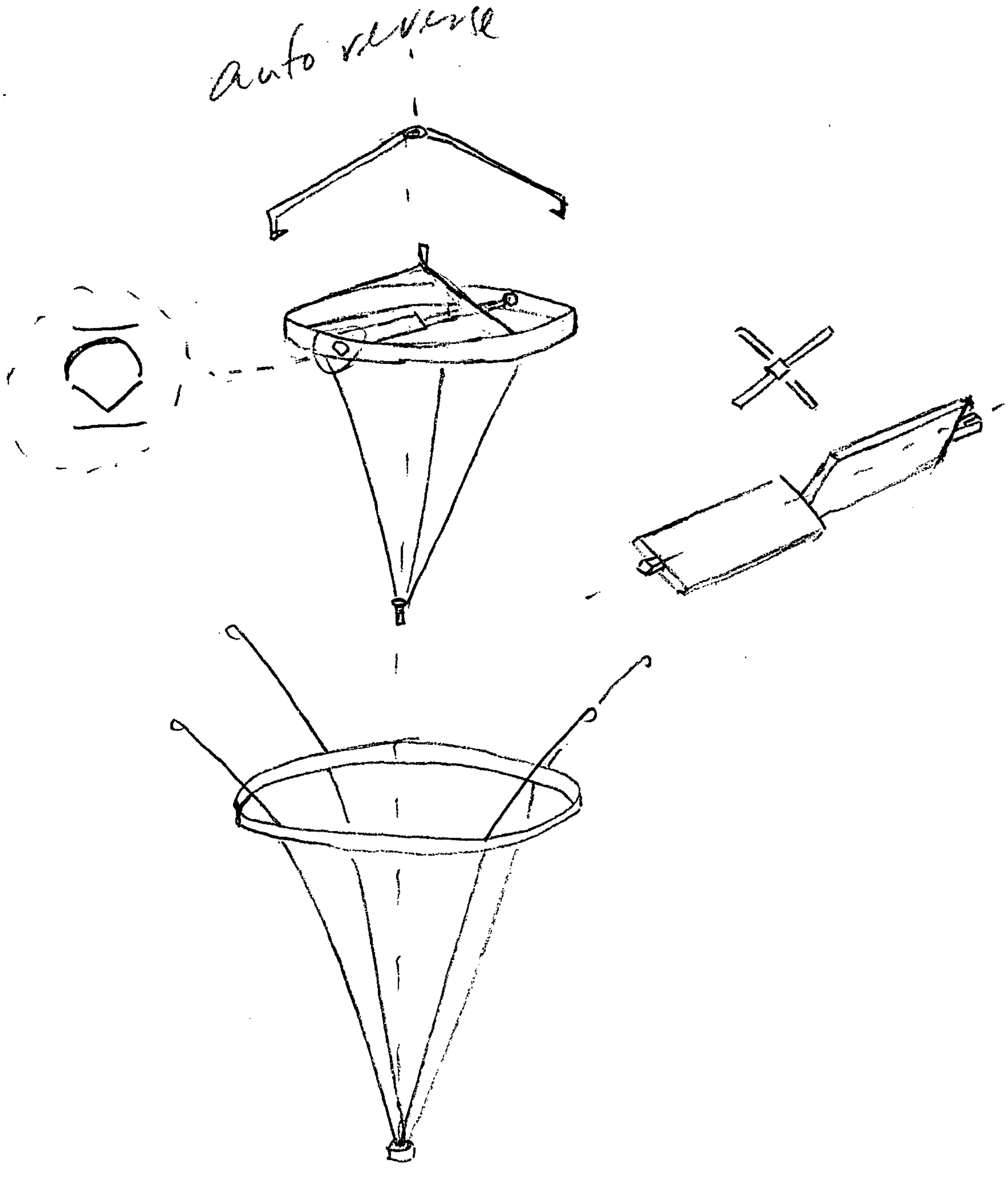


FIGURE 15

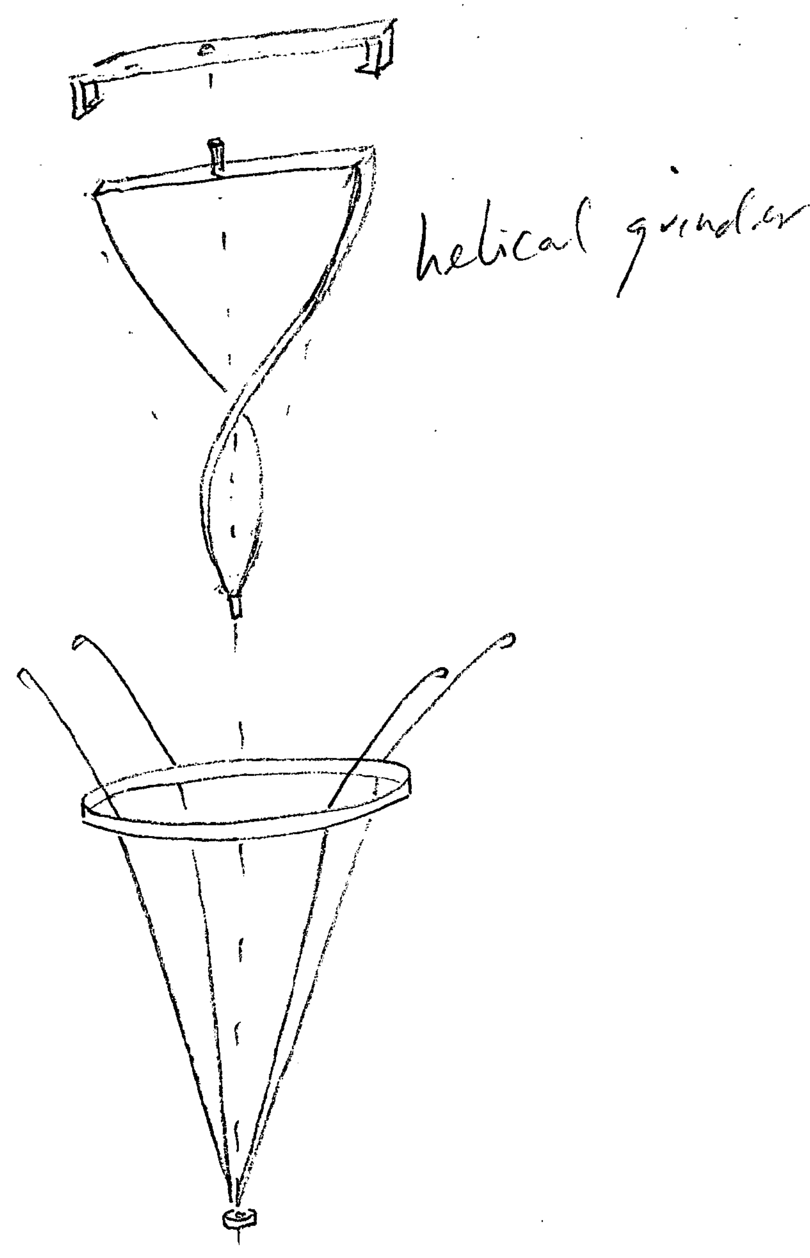


FIGURE 16

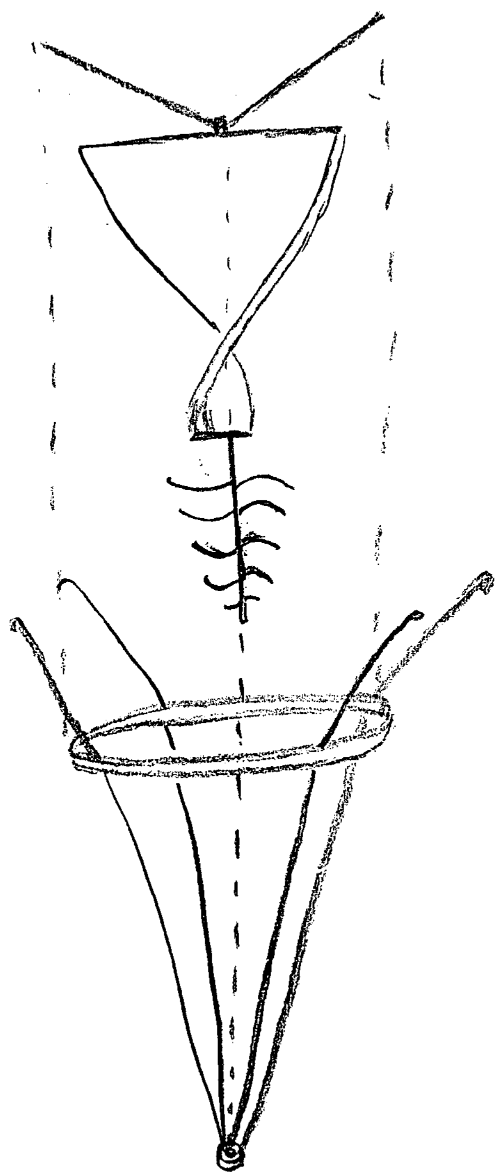


FIGURE 17

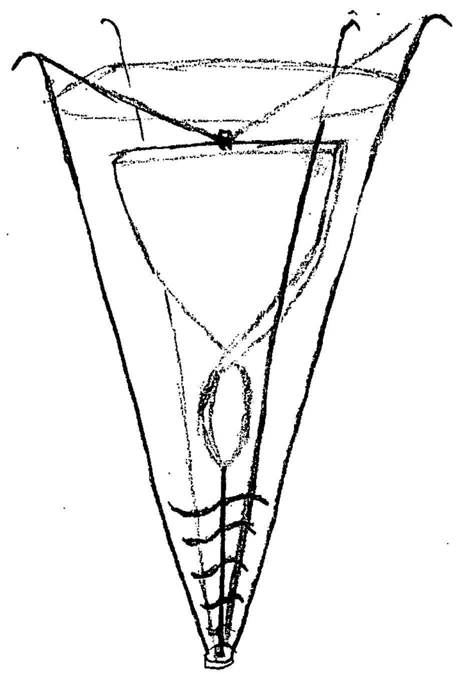


FIGURE 18